DEPARTMENT OF EDUCATION AND SCIENCE

Review of the Present Safety Arrangements for the Use of Toxic Chemicals in Agriculture and Food Storage

Report by the Advisory Committee on Pesticides and Other Toxic Chemicals

LONDON

APPENDIX 2

(PART I)

Membership of the Advisory Committee on Pesticides and Other Toxic Chemicals

Chairman:

Sir James Cook, F.R.S., D.Sc., Ph.D., F.R.I.C., Vice-Chancellor, University of Exeter.

Members:

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*F. J. Aldridge, Esq., Ministry of Health.

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E. H. Bott, Esq., Animal Health Division, Ministry of Agriculture, Fisheries and Food.

W. D. Buchanan, Esq., M.B., Ch.B., B.Sc., D.P.H., Ministry of Labour.

*D. F. Carter, Esq., Board of Trade.

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M. Cohen, Esq., M.Sc., Ph.D., F.I. Biol., Chairman of the Scientific Subcommittee.

J. H. V. Davies, Esq., Food Standards, Science and Safety Division, Ministry of Agriculture, Fisheries and Food.

H. I. Field, Esq., M.Sc., M.R.C.V.S., F.C. Path., F.R.S.A., Chairman of the Veterinary Subcommittee.

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Note: I. Thomas, Esq., C.B.E., M.Sc., Ph.D., F.I. Biol. (Director of the Infestation Control Laboratory of the Ministry of Agriculture, Fisheries and Food) assisted the Committee during the major part of the review.

*These members, who were not appointed until this Report was nearing completion, replaced the following members:

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Mrs. J. A. Hauff, Ministry of Health.

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(PART II)

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The present membership of the Scientific Subcommittee is:

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(PART III)

Membership of the Veterinary Subcommittee

The present membership of the Veterinary Subcommittee is:

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H. I. Field, Esq., M.Sc., M.R.C.V.S., F.C. Path., F.R.S.A., Central Veterinary Laboratory, Ministry of Agriculture, Fisheries and Food.

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Professor E. Boyland, Ph.D., B.Sc., Chester Beatty Research Institute, University of London.

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(PART IV)

Membership of the Working Parties

1. *Working Party on Supply*

Chairman:

Sir James Cook, F.R.S., D.Sc., Ph.D., F.R.I.C., Vice-Chancellor, University of Exeter.

Members:

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E. H. Bott, Esq., Animal Health Division, Ministry of Agriculture, Fisheries and Food.

M. Cohen, Esq., M.Sc., Ph.D., F.I. Biol., Chairman of the Scientific Subcommittee.

J. H. V. Davies, Esq., Food Standards, Science and Safety Division, Ministry of Agriculture, Fisheries and Food.

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Mrs. J. A. Hauff, Ministry of Health.

E. W. Momber, Esq., Department of Education and Science.

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2. *Working Party on Scientific Standards for Clearance of Chemicals or Product.*

Chairman:

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N. W. Moore, Esq., M.A., Ph.D., Natural Environment Research Council (Nature Conservancy).

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3. *Working Party on Use*

Chairman:

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Members:

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4. *Working Party on Residues*

Chairman:

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Secretary:

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APPENDIX 3

Organisations and Individuals who submitted Evidence

Organisations

Agricultural Education Association
Animal Health Trust
*Associated Manufacturers of Veterinary and Agricultural Products
*Association of British Manufacturers of Agricultural Chemicals
Association of County Councils in Scotland
*Association of Municipal Corporations
*Association of Public Analysts
*Association of the British Pharmaceutical Industry
British Bee-Keepers' Association
*British Medical Association
*British Veterinary Association and Royal College of Veterinary Surgeons
Co-operative Wholesale Society Ltd.
*Council for Nature
*Counties of Cities Association
*County Councils' Association
Country Landowners Association
Eastern Regional Board for Industry
*Food Manufacturers' Federation
Forest Products Research Laboratory
Game Research Association
Herbon Ltd.
*Industrial Pest Control Association
Metropolitan Boroughs' Standing Joint Committee
Monsanto Chemicals Ltd.
*National Association of Agricultural Contractors
National Association of Corn and Agricultural Merchants
*National Farmers' Union
National Farmers' Union of Scotland
National Federation of Women's Institutes
*National Union of Agricultural Workers
Paintmakers' Association of Great Britain Ltd.
Paper Sack Development Association Ltd.
People's Dispensary for Sick Animals
Pharmaceutical Society of Great Britain
River Boards' Association
Royal Agricultural Society of England
Royal Entomological Society of London
Royal Horticultural Society
*Royal Institute of Chemistry
Royal Society for the Protection of Birds and British Trust for Ornithology
*Rural District Councils' Association
Seed Trade Association of the United Kingdom
Society of Chemical Industry
Universities' Federation for Animal Welfare
Water Research Association

Individuals who contributed evidence or information

A. M. G. Campbell, Esq., D.M., F.R.C.P.
W. B. Clarke, Esq., M.B., Ch.B., D.P.H., Medical Officer of Health, Newport, Mon.
J. D. Fryer, Esq., M.A., Director of the Weed Research Organisation
F. D. T. Good, Esq., M.R.C.V.S.
B. J. Heywood, Esq., B.Sc., Ph.D., D.I.C., A.R.C.S., F.R.I.C.
A. Hutchison, Esq., O.B.E., M.D., Ph.D., D.P.H., F.R.F.P.S.G., D.P.A., Medical Officer of Health, Kingston upon Hull.
K. Wilson Jones, Esq., Director of Agriculture & Irrigation, Federal Government, Aden.
Professor R. C. Wofinden, M.B., B.S., M.D., D.P.H., M.R.C.S., L.R.C.P., Medical Officer of Health, Bristol.

APPENDIX 4

The Pesticides Safety Precautions Scheme

1. This is a voluntary scheme, agreed between Government Departments (Ministry of Agriculture, Fisheries and Food, Ministry of Health, Department of Agriculture and Fisheries for Scotland and the Scottish Home and Health Department) and the industrial associations concerned (the Association of British Chemical Manufacturers, the Association of British Manufacturers of Agricultural Chemicals and the Industrial Pest Control Association). It came into formal effect early in 1957 under the title "Notification of Pesticides Scheme" although there were informal arrangements from 1954 onwards. The present version, described below, was agreed after a joint review in 1962/63. The Scheme is operated by Government Departments; no charge is made to the notifier except when fish toxicity testing is carried out on his behalf by the Ministry of Agriculture, Fisheries and Food.

2. The purpose of the Pesticides Safety Precautions Scheme is to safeguard human beings (whether they be users, consumers of treated produce, or other members of the public), livestock and domestic animals against risks from all pesticide products used in agriculture (including horticulture and home gardens) or food storage practice in Great Britain and to minimise these risks to wild life. Veterinary products are covered by a parallel Scheme described in Appendix 5. The Scheme is not directly concerned with the efficiency of pesticide products; a separate scheme, the Agricultural Chemicals Approval Scheme, described in Appendix 6, considers the efficiency of pesticide products used in agriculture, and home gardens (but not in veterinary or food storage practice). Under the terms of the Agricultural Chemicals Approval Scheme, however, products containing new active ingredients cannot be approved until the safety in use of their active ingredients has been considered by Departments under the Pesticides Safety Precautions Scheme and any necessary precautions recommended. Similarly, products which have on their labels recommendations for new uses of existing active ingredients cannot be approved until the safety of the new uses has been investigated.

3. Although compliance with the Pesticides Safety Precautions Scheme is voluntary, the vast majority of pesticide products, both home produced and imported, on sale in Great Britain for agricultural and food storage purposes are covered by the Scheme. The majority—but by no means all—of the firms to whom this Scheme applies participate by virtue of their membership of the Association of British Manufacturers of Agricultural Chemicals and/or the Industrial Pest Control Association. Several companies providing an infestation control service are members of the Industrial Pest Control Association and participate in the Scheme but although they represent about 90% of the commercial infestation control service capacity in this country, numerically they probably include not more than 75% of the total number of servicing companies* in the food storage field. This is partly because the majority of the smallest servicing companies are not members of the trade association and partly because their main business may be outside the field of food storage practice although their activities overlap into it. Pesticide products used in food storage practice are used extensively for the control of similar pests and for other purposes in both industry and the home. Those other fields of use are being reviewed separately.

4. The Scheme applies to all pesticide products intended for use in agriculture (other than those used for veterinary purposes), horticulture, home gardens and food storage practice in Great Britain.

5. Under the Scheme distributors undertake to notify:

(a) products containing new active ingredients, i.e. those not previously used in Great Britain as pesticides;

(b) new or existing products intended for uses for which their active ingredients have not been cleared under the Scheme;

(c) products containing an active ingredient which, though not new, is in a new type or strength of formulation, or is applied in a new way or at a greater strength, which could produce a new or increased risk to the user, consumer or others.

They also undertake:

(d) to supply Departments with all information needed to enable them to advise on the precautionary measures which should be employed when such products are used;

(e) not to introduce such new products until agreement has been reached on the appropriate precautionary measures;

(f) to include the agreed precautions, and the common name(s) (or in its/their absence, the chemical name(s)) of the active ingredient(s), on the labels of products offered for sale, and to take all reasonable measures to ensure that others concerned are aware of and, in so far as it lies in their power, observe the precautionary measures advised by Departments;

(g) to withdraw a product from the market if recommended by Departments, on the advice of the Advisory Committee on Pesticides and Other Toxic Chemicals after a review of the safe use of its active ingredient, provided that the notifier has been given every opportunity to make representations to Departments about the recommendations.

6. Notification is not expected while a product is at the stage of laboratory or small-scale trials carried out under the complete control and direction of the distributor. If, however, the product is to be used by agricultural workers subject to the Agriculture (Poisonous Substances) Regulations, or if treated produce from such trials is to be made available for human or animal consumption, the product must first be notified. Notifiers are given, in the Appendices and Working Documents published in the Pesticides Safety Precautions Scheme, general advice on the form a notification should take and guidance on the type and extent of data required. They are also advised to consult the appropriate Ministry Laboratory at an early stage so that when a notification is made, the information accompanying it is as complete as can reasonably be expected. Notification may be withdrawn at any stage without prejudice to any future re-notification.

7. Before a new product is marketed or brought into commercial use, or the extended use of an existing product is recommended, the distributor submits a notification to the Ministry of Agriculture, Fisheries and Food, in the person of the Director of the Plant Pathology Laboratory for pesticide products intended for use in agriculture (excluding veterinary use), horticulture and home gardens or the Director of the Infestation Control Laboratory for pesticide products for use in food storage, for domestic use, and for use against wild birds and animals including rodents. The appropriate staff of the Laboratories service the Scientific Subcommittee (see below).

8. Under the authority of the Director concerned, the appropriate staff of the Laboratory arranges for a notification to be dealt with in one of the following ways:

(a) by the Laboratory itself. In such cases the Laboratory usually transmits its recommendations to the appropriate administrative divisions of the Agriculture and Health Departments in England and Wales, and Scotland. The appropriate Division of the Ministry of Agriculture, Fisheries and Food co-ordinates the views of all four Departments and transmits the recommendations (with any amendment) to the notifier on behalf of all these Departments.

(b) by the "quick procedure" under which the appropriate staff of the Laboratory

consultation confirms that the notification can be dealt with in this way, proposed recommendations for its clearance are sent to Departments and dealt with as above;

(c) by the Committee procedure under which copies of all the notifier's data and a paper, prepared by the Scientific Subcommittee's Secretariat and containing draft recommendations for consideration, are sent to the Scientific Subcommittee. The Subcommittee makes recommendations either to the Advisory Committee which then advises Departments or, under authority delegated to it, direct to Departments as in (a) above. Whichever course is taken the appropriate Division of the Ministry of Agriculture, Fisheries and Food co-ordinates the views of all four Departments and transmits the recommendation (with any amendment) to the notifier on behalf of all these Departments concerned.

9. Products notified under the Scheme may be given any of the following clearances:

(a) *Trials clearance*

This is normally given for a limited period, e.g. one season or year, to enable field trials to be carried out on one or more crops or for the product to be tried out on a limited scale on or near stored foodstuffs. At the end of this period certain requirements, e.g. the provision of residue data, have to be met but the notifier may, on request, be given a trials clearance for a further period without supplying these data if the extent and scope of the trials do not exceed those for which clearance was originally given. The product may not be sold for the purpose of these trials and application must be by the notifier's personnel or certain other specified categories of worker. There may be restrictions on the disposal of treated edible crops or foodstuffs until adequate residue data have been submitted and accepted by Departments.

(b) *Limited clearance*

This is usually given for one season or year only, at the end of which the notifier is required to report back with additional information e.g. on hazards to wild life. Clearance may be extended for a further period on similar conditions to a trials clearance. The notifier may sell the product, up to a limited quantity, to the growers or warehouse keepers concerned but he may be asked to keep a record of those to whom he supplied it and instruct them in its safe use. There may also be restrictions on the disposal of treated edible crops etc.

(c) *Provisional commercial clearance*

This permits the notifier to sell his product freely on the open market, subject to the labelling and other conditions agreed by Departments, for a stated period, usually 1 or 2 years. At the end of this time requirements for the provision of additional information e.g. confirmatory residue data, must be met.

(d) *Commercial clearance*

This permits the notifier to sell his product on the open market subject to any labelling and other conditions agreed by Departments.

10. In the case of (c) and (d) above, Departmental recommendations for the safe use of the product's active ingredient(s) are normally published by the Ministry of Agriculture, Fisheries and Food and given a wide circulation both in this country and abroad, but the notifying firm is first invited to accept them. If the firm is unable to do so, the Ministry of Agriculture, Fisheries and Food gives the reasons for the disputed precautions in writing and the firm is given an opportunity for further discussion with the Ministry before a final decision is taken.

11. Separate Recommendations Sheets are published for agricultural (other than veterinary)

Each Recommendations Sheet normally applies only to one active ingredient but some cover a group of active ingredients for a particular use, e.g. organomercury dry seed dressings. Active ingredients are normally referred to by their British Standards Institution common name but when there is no common name the chemical name is used with a footnote giving the name of the proprietary product in which it is contained. Only in rare cases is the proprietary name used throughout a sheet for simplification.

12. Except for a slight variation for rodenticides, precautions are listed under three headings: (i) Protection of Operators or Users; (ii) Protection of Consumers; (iii) Protection of Livestock, Wild Life and Others. Phrases giving warnings of risks and describing the safety precautions to be taken which must appear on the label, are given under headings (i) and (iii). Section (ii) on Protection of Consumers, contains no labelling phrases but gives general information about the crops or foodstuffs to which the active ingredient may be applied and the minimum interval to be observed between last application and harvesting or processing. The gist of this must appear on the label of all products containing the active ingredient. Where sufficient residue data are available a maximum expected residue level is included. It is usual to include where necessary a reference to other regulations, handbooks, or codes of practice which should be consulted before using a particular chemical. A note appears on sheets for provisional commercial clearances drawing attention to the provisional nature of the recommendations and stating the date of their review. Each sheet bears a date of issue.

13. Recommendations for the safe use of any active ingredient may be reviewed if valid evidence arises from any source that its use is responsible for, or appears to be responsible for, a hazard or degree of risk which is novel or was not recognised at the time of notification. Active ingredients in products already on the market when the original Notification Scheme was introduced, and for which no official safety arrangements have yet been issued by Departments are known as "backlog chemicals". These are being reviewed in turn.

14. The appropriate staff of the Laboratory, the Advisers, the Scientific Subcommittee and the Advisory Committee all need scientific information on the pesticide product to help them in formulating these recommendations on its safe use. The scientific standards applied to this information are either set out directly or implied in the Appendices and Working Documents to the present Pesticides Safety Precautions Scheme which are published in full in the Scheme and listed below:

(1) Scientific standards in the presentation of general information.
Appendix A; information guide and notifying letter.
W.D. No. 1; summary data sheet format.

(2) Scientific standards in the assessment of toxicity.
Appendix B; toxicity data guide.
W.D. No. 2; tests for neurotoxicity or organophosphorus compounds.
W.D. No. 3; screening organophosphorus anticholinesterase compounds for response of reactivating agents.

(3) Scientific standards in the assessment of carcinogenicity.
Appendix F; carcinogenicity guide.

(4) Scientific standards in the assessment of residue risks.
Appendix C; residue guide.
W.D. No. 5; presentation of residue data.

(5) Scientific standards in assessing risks to wild life.
Appendix D; provision of information about effects on wild life.
W.D. No. 4; assessing the short-term risks to birds from pesticides.

(6) Scientific standards underlying guidance on labelling.

Appendix E; labelling guide.

W.D. No. 7; standard phrases for commercial agricultural and horticultural use.

W.D. No. 8; standard phrases for home garden use.

W.D. No. 9; medical advice on labels (for organophosphorus compounds).

W.D. No. 10; standard phrases for industrial and domestic pesticides.

W.D. No. 11; standard phrases for retail sale of domestic pesticides.

W.D. No. 12; safety code for commercial pesticides used by servicing operators in the course of their duties.

(7) Scientific standards underlying types of clearance granted.

Appendix G; types of clearance given.

APPENDIX 5

The Veterinary Products Safety Precautions Scheme

1. The Veterinary Products Safety Precautions Scheme was introduced, with the agreement of industry, in February 1964, because the Advisory Committee and Departments agreed that a scheme, separate from what is now the Pesticides Safety Precautions Scheme, was needed to cover the many products available for the treatment of animals.

2. At its outset it was agreed that the Scheme should apply to veterinary products available directly to a farmer, and not to those obtainable only through or on prescription of a veterinary surgeon or veterinary practitioner. Initially, those antibiotics and hormonal preparations which were subject to other controls were to be excluded from the Scheme but it was agreed that it might be extended in due course to cover any substance used for veterinary purposes. Recently the Scheme has, in fact, been extended to cover hormonal products.

3. The purpose of the Scheme is to safeguard human beings (whether they be users, consumers of food substances from treated animals, or other members of the public), livestock, domestic animals and wild life, against risks from veterinary products.

4. In practice it was discovered that not all antibiotics and hormonal preparations intended for veterinary use were in fact receiving adequate control and, in consequence, the Veterinary Subcommittee has accepted certain notifications of such products as, for example, tylosin (an antibiotic) and stilboestrol (an hormonal product) on an *ad hoc* basis. This led to the extension of the scope of the Scheme referred to in para. 2 above. For similar reasons, a few "fringe products" e.g. insecticides used in animal houses, preparations used in dairy hygiene and simple food additives also have received consideration.

5. The exact percentage of distributors of veterinary products who participate in the Scheme is not known, but the degree of compliance appears to be satisfactory.

6. The Veterinary Products Safety Precautions Scheme is run on very similar lines to the Pesticides Scheme, described in Appendix 4. Applications are subject to scientific scrutiny by the Veterinary Subcommittee of the Advisory Committee on Pesticides and Other Toxic Chemicals.

7. Other differences in procedure are as follows:

(a) Notifications in respect of veterinary products are sent to the Technical Secretary of the Veterinary Subcommittee, who is a member of the professional staff of the Central Veterinary Laboratory of the Ministry of Agriculture, Fisheries and Food.

(b) General guidance on the form a notification should take is published in Appendices A and B to the Veterinary Products Safety Precautions Scheme. More detailed advice to the notifier is given by the Technical Secretary on the lines of the published Appendices and Working Documents of the Pesticides Safety Precautions Scheme.

(c) If the Director of the Central Veterinary Laboratory considers that a particular notification need not await meetings of the Veterinary Subcommittee and the Advisory Committee, a "quick procedure" is used instead. Under this procedure copies of all the relevant papers are sent to members of the Veterinary Subcommittee and, if their comments confirm that the product might be cleared without awaiting meetings of either the Subcommittee or the Advisory Committee, draft recommendations are

replies, the Ministry of Agriculture, Fisheries and Food informs the notifier either of the agreed recommendations for safe use or that the notification will have to be referred to the Committees.

(d) Recommendations for the safe use of veterinary products are, in the majority of cases, issued under the name of the proprietary product rather than its active ingredient(s).

(e) Clinical trials are authorised, sometimes with a large number of animals, and take the place of the "limited clearance" in the Pesticides Safety Precautions Scheme.

APPENDIX 6

Agricultural Chemicals Approval Scheme

1. The Agricultural Chemicals Approval Scheme is a voluntary scheme under which proprietary brands of pesticide products used for plant protection by farmers, growers and amateur gardeners can be submitted, on payment of a fee, for official approval of their biological efficiency. The purpose of this scheme is to enable users to select, and advisers to recommend, efficient and appropriate pesticide products for use against particular pests, diseases and weeds and to discourage the use of unsatisfactory products. The scheme covers only those pesticide products used for the control of plant pests and diseases, for the destruction of weeds, for growth regulation, and other plant protection purposes. It does not cover veterinary products, rodenticides, or other pesticide products used for food storage, or domestic purposes.

2. The scheme is operated by the Agricultural Chemicals Approval Organisation on behalf of the Agricultural Departments of the United Kingdom. Approval is granted by the Organisation for specific uses, under United Kingdom conditions, only when the Organisation is satisfied that the product fulfils the claims made on the label. These claims are subject to constant review.

3. The scheme does not deal directly with the operator and consumer safety requirements, but approval of the efficiency of a pesticide product containing a new active ingredient or involving a new use of an existing active ingredient cannot be given until the use of that active ingredient has first been considered and cleared for safety under the Pesticides Safety Precautions Scheme. Approved products (as distinct from those cleared *only* for safety under the Pesticides Safety Precautions Scheme) bear the "A" symbol on the label. A list of Approved Products for Farmers and Growers is issued annually in February. Pesticide products approved specifically for use by amateur gardeners are included in the booklet "Chemicals for the Gardener" published by H.M.S.O.; this booklet is periodically reviewed.

4. It is the responsibility of the manufacturers to provide the data on which approval is considered. Other data obtained independently either through the N.A.A.S. or the Agricultural Research Stations are to supplement the manufacturers' data, but not to replace them.

APPENDIX 7

Legislation in Great Britain

(This appendix contains short descriptions of legislation which concerns pesticide and veterinary products. It is intended to give a broad general indication of their scope; it is neither exhaustive nor comprehensive.)

Part I—The Agriculture (Poisonous Substances) Act 1952

1. This Act (as extended by the Agriculture (Poisonous Substances) (Extension) Orders of 1960, 1965 and 1966) and the Regulations made thereunder are administered in England and Wales by the Minister of Agriculture, Fisheries and Food and, in Scotland, by the Secretary of State. The purpose of the Act is to protect agricultural employees from poisoning by the more dangerous pesticide products. Its provisions do not extend to self employed persons or to members of the general public.

2. The present Regulations name 37 active ingredients; group them into four classes; specify 17 operations in which products containing these active ingredients could be handled or used; and list the type of protective clothing which must be worn according to the class of the active ingredient and the nature of the operation. For example an employee opening a container of demeton (a class 1 active ingredient) must wear rubber gloves, rubber boots, respirator and either an overall and rubber apron or a mackintosh. The Regulations take into account the fact that one method of using a chemical may be inherently more dangerous to the operator than another; other things being equal, soil application is safer than outdoor spraying, which in turn is safer than the use of aerosols under glass.

3. The Regulations impose obligations on both employers and employees. For example, the employer must provide the prescribed protective clothing and make certain that the employee wears it, while the employee must wear the clothing provided. The Regulations also cover the maximum number of hours workers may carry out scheduled operations; the age at which they may be employed; precautions to be taken when working in greenhouses; the maintenance of protective clothing; the provision of washing facilities; the notification of sickness; the training and supervision of workers carrying out scheduled operations; the provision of drinking water and vessels; the need to ensure that tanks and containers for storing pesticide and veterinary products containing scheduled active ingredients are securely closed when not in use; and the keeping of a register containing details of all scheduled operations carried out on ground crops, or on bushes, climbing plants (including hops) and trees, or in greenhouses, where these exceed specified acreages.

4. The Act and Regulations are enforced by Safety Inspectors who have rights of entry on to land and can require the production of the register containing details of the scheduled operations performed and take samples of products for independent analysis. They give advice in connection with the precautions to be observed. Inspectors may also grant, on specified conditions, certificates of exemption from any of the provisions of the Regulations if they are satisfied either that the worker can be adequately protected by other precautions or that the provisions are unnecessary under the proposed conditions of use.

5. The Ministry of Agriculture, Fisheries and Food and the Department of Agriculture and Fisheries for Scotland issue a leaflet APS/1 'The Safe Use of Poisonous Chemicals on the Farm', which includes a valuable summary in non-legal terms of the main provisions of the Regulations, as well as much general advice on the safe use of pesticide products in relation to persons, livestock and wild life; the cleansing and maintenance of respirators and dust masks; notes on the [illegible] the necessity for constant medical supervision of workers. This leaflet also contains a list of addresses of regional and divisional inspectors appointed under the Act.

Part II—The Hydrogen Cyanide (Fumigation) Act, 1937

6. This Act is administered in England, Wales and Scotland by the Home Secretary. The Act, and the Regulations made under it in 1951 provide protection to operators and third parties during and following the fumigation of buildings or ships with hydrogen cyanide for the control of pests of foodstuffs and in public health. They do not apply to fumigation with cyanide in the open air (e.g. against rabbits), to the fumigation of grain by means of calcium cyanide, or to fumigation for horticultural purposes in a building not used for human habitation.

7. The Regulations lay down the qualifications required of persons undertaking fumigations with hydrogen cyanide, describe the way in which searches must be made for unsuspecting persons within buildings which are about to be fumigated, and require warning notices to be posted. There are also safety requirements relating to the manner in which the fumigant is generated, the safety of the operators in the process of fumigation, and the containers which hold the fumigant.

8. The Regulations require the disposal of residues from substances and of apparatus used in fumigation and that, after a period of ventilation, the atmosphere must be tested to ensure that it is cleared of any dangerous concentrations of the fumigant.

9. Prior to a fumigation, notification must be given to the police (or to the harbour authority, when the fumigation takes place within its area) and the medical officer of health must also be informed. The same officials must be informed when the fumigation is complete. There are special provisions for the fumigation of foodstuffs; permission must be obtained from the medical officer of health and the fumigation is subject to such conditions as he may prescribe for preventing the contamination of foodstuffs. (For certain purposes application must be made to a person designated by the Minister of Agriculture, Fisheries and Food or, in Scotland, by the Secretary of State.)

10. A report of the fumigation must be sent by the person undertaking the fumigation to the Home Secretary within thirty one days of its completion. He must, under the Act, be given notice of all accidents whether fatal or otherwise, and he may direct an enquiry to be made into any accident. The Home Secretary also has powers to establish a court to conduct an inquiry, and to adjourn any coroner's inquest into a death following the use of hydrogen cyanide until he has appointed someone to observe the proceedings. He can also appoint persons with the right of entry and inspection of any premises which are the subject of an inquiry, and the right to inspect all relevant books, papers and documents. Evidence may be taken under oath for the purposes of conducting such an enquiry.

11. So far as the use of pesticide products is concerned, this Act currently provides the only attempt to define what is meant by an experienced operator. Under this Act at least two persons are required to carry out a hydrogen cyanide fumigation and the main operator must, during the preceeding two years, have been engaged in fumigations with this material on not less than twenty occasions, of which not less than six shall have been concerned with the fumigation of buildings. A subordinate member of the staff other than the main operator shall, during the preceding six months, have engaged in fumigation on not less than six occasions.

Part III—The Pharmacy and Poisons Act, 1933

12. The active ingredients of some pesticide and veterinary products are covered by the Pharmacy and Poisons Act, 1933. This Act, and the Poisons Rules made under it, is administered in England and Wales and in Scotland by the Home Secretary who is advised by a committee called the "Poisons Board".

13. Scheduled poisons are included in a "Poisons List". Broadly, Part I of the list names poisons which may only be sold retail by an "authorised seller of poisons" (e.g. a registered pharmacist) and Part II names those which may be sold by either an authorised seller or a "listed seller" i.e. a person on the list, kept by a local authority, of persons who are entitled to sell Part II poisons. Exemptions are however made in the case of supply of a poison by, for example, a registered veterinary surgeon for veterinary purposes. Part II poisons are normally those which are in common use for non-medicinal purposes or which are likely to come into such use.

14. The Act includes general provisions for the labelling and sale of scheduled poisons.

15. The Poisons Rules, made under the Act, contain detailed provisions regarding restrictions on sales by authorised and listed sellers, the colouring of certain poisons, the labelling of containers, the form of containers, the manufacture, storage and transport of poisons, and other matters.

16. The Schedules to the Poisons Rules contain special provisions relating to the sale of poisons listed in these Schedules. For example, Schedule 4 lists poisons which may be sold retail only on a prescription by a duly qualified medical practitioner, registered dentist, registered veterinary surgeon or registered veterinary practitioner; Schedule 5, Part A, states the form in which specified poisons are restricted when sold by listed sellers of Part II poisons and Schedule 5, Part B, names poisons which may be sold by listed sellers of Part II poisons only to persons engaged in the trade or business of agriculture or horticulture and for the purpose of that trade or business.

17. When Departments decide that a particular active ingredient shall be regulated under the Agriculture (Poisonous Substances) Regulations, the Secretary of the Poisons Board is advised accordingly so that consideration can, if necessary, be given to its inclusion in the Poisons List and Rules.

Part IV—The Protection of Animals and of Birds Acts

18. It is an offence in England and Wales under the *Protection of Animals Acts 1911 to 1927* and in Scotland under the *Protection of Animals (Scotland) Act 1912* (administered by the Home Secretary and Secretary of State for Scotland respectively) to place in or on any land or building any poison or any edible matter (other than sown seed or grain) which has been rendered poisonous. It is however a defence that the poison was placed by the accused for the purpose of destroying vermin (described in the *Amendment Act of 1927* as 'insects and other invertebrates, rats, mice or other small ground vermin') where this is found necessary in the interests of public health, agriculture or the preservation of other animals or for the purpose of manuring the land and that all reasonable precautions were taken to prevent injury to dogs, cats, fowls and other domestic animals and wild birds.

19. Notwithstanding this proviso, the *Animals (Cruel Poisons) Act 1962* permits the Home Secretary to prohibit by Regulation the use in England, Wales and Scotland of any named poison for the purpose of destroying mammals of any description if he is satisfied that it could not be used for destroying mammals without causing them undue suffering, and that other suitable methods of destroying them exist, and are, or would in certain circumstances be, adequate.

20. Regulations made in 1963 under this Act prohibit the use of elementary yellow phosphorus and red squill (the powder or extract derived from the red variety of *Urginea maritima (L)*) in or upon any land or building for destroying mammals of any description. The use of strychnine except for the control of moles is similarly prohibited: its use for the control of seals is still permitted so long as the bait is put in nets at sea.

21. Under the *Protection of Birds Act, 1954* which is the responsibility of the Home Secretary, it is an offence to kill or take any wild birds or their eggs in England, Wales and Scotland; but the Second Schedule to the Act names species (mainly regarded as pests) which may be killed or taken at any time by an authorised person—usually the owner or occupier of land on which action is taken. Under Section 10 a licence may be granted for killing or taking birds for specified purposes and the Minister of Agriculture, Fisheries and Food (in Scotland, the Secretary of State) may grant licences for killing or taking Second Schedule birds by the use of poisoned or stupefying baits. Save under licence it is an offence (under Section 5) to use poisoned or stupefying bait, or traps or devices calculated to cause bodily harm to any wild bird, or for the purpose of taking or killing any wild bird; except that it shall be a defence that the article was set in position for the purpose of taking animals in the interests of public health, agriculture or the preservation of other creatures, and that all reasonable precautions were taken to prevent injury thereby to wild birds.

Part V—The Agriculture (Safety, Health and Welfare Provisions) Act, 1956

22. This Act and the Regulations made thereunder are administered in England and Wales by the Minister of Agriculture, Fisheries and Food and in Scotland by the Secretary of State. The purpose of the Act is to prevent accidents to agricultural workers and to children.

23. Although the Act and Regulations made under it make no specific reference to the use of pesticide and veterinary products, sprayers, and soil application and granule placement machines are included in the machines which are the subject of the Agriculture (Field Machinery) Regulations. These Regulations provide for the guarding of specified moving parts of field machines and the marking of hydraulic and pneumatic valves and cocks. They also require a field machine to be so maintained that it is safe for an operator to use. The Regulations are enforced by Safety Inspectors who also pay regard to the chemical risks of operating a machine used for the application of pesticide and in rare cases, veterinary products.

Part VI—Legislation regarding the pollution of streams and other waters

24. *The Rivers (Prevention of Pollution) Acts 1951 to 1961* which are the responsibility of the Minister of Housing and Local Government, and the corresponding Scottish Acts of 1951 and 1965, which are the responsibility of the Secretary of State for Scotland, make it an offence to cause poisonous, noxious or polluting matter to enter a stream. River Authorities (River Purification Boards in Scotland) have power under the Acts of 1951 to make byelaws to prohibit or regulate the putting into a stream of objectionable matter, whether polluting or not. "Streams" include any river stream or watercourse or inland water discharging into a stream.

25. *The Salmon and Freshwater Fisheries Acts 1923 to 1965* which is the responsibility of the Minister of Agriculture, Fisheries and Food, and *Salmon Fisheries (Scotland) Act 1862 and the Salmon and Freshwater Fisheries (Protection) (Scotland) Act 1951* make it an offence to put any liquid or solid matter into fishing waters with the result that the waters are rendered poisonous or injurious to fish. (There are reservations where the offender can show that he has taken all possible preventive action.) The same Acts make it possible to introduce poisons and noxious substances into fishing waters for a scientific purpose, or for the purpose of protecting, improving or replacing stocks of fish but such uses require the permission in writing of appropriate authorities. "Fishing waters" include all waters in which fish exist, including ponds and lakes.

26. Under the *Water Resources Act 1963*, which is the general responsibility of the Minister of Housing and Local Government, a River Authority in England and Wales may take any emergency measures it thinks necessary when polluting matter gets into water in its area as a result of an accident or similar cause. There is no corresponding legislation in Scotland.

Part VII—The Food and Drugs Acts

27. The Food and Drugs Act 1955 applies to England and Wales and is administered jointly by the Minister of Agriculture, Fisheries and Food and by the Minister of Health;

administered by the Secretary of State for Scotland and the Minister of Health and Social Service for Northern Ireland. Their main purpose is to ensure that food sold to the public is free from contamination and harmful ingredients and is fit for human consumption.

28. Authorised officers of enforcing authorities, which in the main are local and port health authorities, have powers of entry, inspection and sampling.

29. For the purposes of these Acts 'food' is defined as excluding live animals (section 135(1)*). Although the question is not specifically dealt with in the Acts and does not seem to have been decided by the Courts, it could also be argued that, as humans do not eat growing crops, these also cannot be regarded as 'food' within the meaning of the Acts. It is therefore certain that the Acts cannot be used directly to control the use of toxic chemicals on live animals and it is probable that the position as regards growing crops is the same. The Acts can, however, be brought to bear once the animal has been slaughtered or the crop harvested, so becoming 'food'.

30. The Acts make it an offence to add a substance to food, or to subject food to a process or treatment, if the food is thereby made injurious to health and if it is to be sold for human consumption (section 1); but, because of the meaning of 'food' for the purposes of the Acts, this particular provision affords no protection in the case of an animal product which became contaminated before the animal was killed nor, probably, in the case of a vegetable product which was treated when it was a growing crop.

31. The Acts also make it an offence to sell food which is unfit for human consumption, irrespective of the stage at which it became unfit (section 8), or to sell to the prejudice of the purchaser food which is not of the nature, substance or quality demanded (section 2).

32. The provisions of sections 8 and 2 (and of section 1 if it applies) should be effective where the enforcing authority is in a position to prove beyond all reasonable doubt that a harmful residue is present in the food. But it is unlikely that the Acts could be used to maintain an ample margin of safety unless regulations are made specifically for that purpose (under section 4). Regulations may set upper limits for the amounts of residues which may be present in food or may entirely prohibit the presence of a particular residue or class of residue.

33. Regulations specifying the amount of arsenic and lead allowed in food are already in force. Both these substances may of course be present in the residues of pesticide and veterinary products that contain them. The regulations which control the use of preservatives in food apply incidentally to any agricultural chemicals, such as thiourea, which have a preservative effect on food. A great many chemicals used in agriculture are, however, outside the scope of these controls.

34. Sampling may be at any stage in the chain of distribution (section 91) and there is a special provision in the Acts which enables the person from whom the sample was taken, if charged with an offence, or the enforcing authority, to bring before the Courts some other person whose act or default was the cause of the contravention (section 113). This provision can be used to secure the conviction of the person really responsible for the offence having been committed, for example, the farmer or grower who misused the toxic chemical in the first place. In practice, however, it would often be impossible to prove who the real offender was, so that the only person whom the Court could convict would be the distributor from whom the sample was taken.

35. The Acts also contain provisions about warranties which sometimes enable responsibility for a contravention to be passed back along the chain of distribution. If a trader buys an article of food under a written warranty to the effect that it can lawfully be sold, he is, subject to certain conditions laid down in the Acts, entitled to be acquitted if the sale of the food proves subsequently to be an offence (section 115). A complementary provision makes it an offence to give a false warranty unless, when it was given, there was reason to believe that it was accurate (section 116(2)).

36. These Acts will, of course, afford protection to the consumer only if the foods likely to be contaminated are adequately sampled and are tested by the analyst for a wide range of possible contaminants. The enforcing authorities, who meet the expense, have discretion to decide the range of the sampling and testing they undertake.

their occupancy of any particular post with no deputies or alternates allowed. We recognise that, given the wide remit of the advisory committee, some disciplines may not be adequately represented on the subcommittees. We think that, at least in the immediate future, this could best be dealt with by extending the present practice of inviting additional experts for the discussion of particular items of business.

*Descriptions, labelling and advertisements**

44. We have considered whether each specific label should be approved as part of the licence. We think that a proper control of labelling could best be achieved in this way and we *recommend* that consideration be given to including such a provision in the mandatory scheme. We realise however that it may be thought that this would be too time-consuming or would unnecessarily restrict the applicant for a licence in the design of his labels. An alternative method would be to grant Ministers power to control labelling by general regulations and in this event we *recommend* that the power should be given in similar terms to Section 7(1) of the Food and Drugs Act, 1955 which reads: "The Ministers may make regulations for imposing requirements as to, and otherwise regulating, the labelling, marking or advertising of food intended for sale for human consumption and the descriptions which may be applied to such food."

45. General regulations might make it compulsory to include on labels, for example, the licence number; the common name—as approved by the British Standards Institution or the Pharmaceutical Society of Great Britain—or, in the absence of a common name, the full chemical name of the active ingredient; the concentration and, if appropriate, the chemical classification of the active ingredient; the necessary safety precautions and any agreed toxicity marks or symbols which might include a colour code. There might also be regulations governing the size of type to be used and the nature of the container for pesticide and veterinary products containing specified active ingredients or classes of active ingredients.

46. We think the licensing authority should have power to prevent the use of objectionable or misleading names, for example the use of names which are similar sounding for products of an entirely different chemical nature. We *recommend* accordingly.

47. As for advertisements, regulations might be needed to require specification of the active ingredient and to prevent misleading claims and misleading uses of words like "safe", "non-poisonous" and "harmless".

Control of sales outlets

48. At present, pesticide and veterinary products may be sold without restriction except for those containing poisons scheduled under the Pharmacy and Poisons Act 1933 and the Poisons Rules and List. Certain other substances used for veterinary purposes, controlled by other legislation, do not fall within our present survey. Broadly, except in the case of poisons supplied for animal treatment by a registered veterinary surgeon or a registered veterinary practitioner or a manufacturer registered with the Pharmaceutical Society, poisons scheduled under Part I of the Poisons List may be sold only by an authorised seller such as a pharmacist. The purchaser must be known to the seller to be a person to whom the poison may properly be sold and details of the sale must be recorded in a poisons book and the entry signed by the purchaser. There is therefore little chance of amateur users getting hold of Part I substances.

49. Special restrictions apply in the case of strychnine and organofluorine compounds which are scheduled as Part I poisons. They may be sold only by authorised sellers and to persons holding a permit, issued by a specified competent authority, stating the purpose and place of use of the poison and the amount to be purchased.

50. It is one of our present duties as an advisory committee to recommend which of the substances under our consideration should be included in the Poisons List. We consider that the arrangements for controlling the supply of Part I substances are adequate and no alteration is required in this system.

51. Poisons scheduled under Part II of the Poisons List may generally be sold only by authorised sellers or by "listed sellers" i.e. persons authorised by a local authority. These poisons are divided into categories to which different provisions apply. For example, when sold by listed sellers, poisons listed in Schedule 5A of the Poisons Rules must be in the form specified e.g. endrin and endosulfan may be sold to anyone but only in preparations for use in 'agriculture and horticulture'. On the other hand, poisons listed in Schedule 5B, may be sold in any form but only to persons engaged in "agriculture or horticulture" and for the purpose of that trade or business. While therefore a householder could not obtain supplies of those organophosphorus compounds which are listed under Schedule 5B, he could, if he wished, legally obtain and use in his garden supplies of endrin, which is included under Schedule 5A.

52. Endrin and a number of organophosphorus compounds are among the active ingredients listed under the Agriculture (Poisonous Substances) Regulations because they are particularly hazardous to use. Under these Regulations, farmers must ensure that employees using listed active ingredients are supplied with and wear prescribed protective clothing. None of the active ingredients listed in these Regulations should be obtainable by home gardeners and other amateur users except in low concentrations suitably packed and exempted from the Regulations. We therefore *recommend* that poisons in concentrations covered by the Agriculture (Poisonous Substances) Regulations and which are also scheduled under the Poisons List should be sold only to commercial users.

53. We see no cause to make any further restrictions on sales outlets. The best protection of the public where less toxic pesticide and veterinary products are concerned is through adequate and informative labelling.

Transitional arrangements

54. If the form of control we have proposed is adopted, it would be necessary to allow a period between the passing of the necessary legislation and its coming into force. In this period pesticide and veterinary products containing active ingredients whose use had been cleared under the existing safety schemes would be granted licences, based on the agreed recommendations for safe use. Pesticide and veterinary products containing new active ingredients would be dealt with under the

"backlog" active ingredients (described in paragraphs 20 and 21) would also be granted licences during this period but, in deciding the conditions of such licences, the licensing authority would need to consider in particular whether the licences should be issued subject to review or renewal within a specified length of time. All licences prepared during this period would take effect from the date on which the new arrangements came into force. We *recommend* accordingly.

III. INFORMATION REQUIRED BEFORE A LICENCE IS ISSUED OR A PRODUCT CLEARED AND THE SCIENTIFIC STANDARDS BY WHICH THAT INFORMATION IS JUDGED

Appendices and Working Documents to existing Schemes

55. The Appendices and Working Documents to the Pesticides Safety Precautions Scheme* give details of the information required by Departments under that scheme before clearance can be given. They also describe ways in which such information may be obtained. The Appendices to the Veterinary Products Safety Precautions Scheme* contain only a brief outline of the requirements for veterinary products but the detailed documents attached to the Pesticides Safety Precautions Scheme are adapted as necessary.

56. We have examined the standards set or implied in these Appendices and Working Documents and have considered whether there is any need for a change in the quality and quantity of the scientific information required and in the methods of using it for assessing hazards. We do not think any radical changes are required, particularly since in recent years there has been a progressive raising of standards before products and active ingredients have been recommended for commercial clearance under the present voluntary arrangements. We *recommend* however that the appendices and working documents (or their equivalent) which will be required in any new scheme should between them cover both pesticide and veterinary products.

57. We think some rearrangement of the documents concerned is desirable to relate corresponding Appendices and Working Documents. We *recommend* the arrangement set out in para. 14 of Appendix 4.

Mammalian toxicity

58. The Toxicity Data Guide to the Pesticides Safety Precautions Scheme and the existing working documents on neurotoxicity† testing of organophosphorus compounds and on the screening of organophosphorus anticholinesterase† compounds for response to reactivating agents† are generally satisfactory, although they will need some revision in the light of new knowledge. Further information could be supplied on the chronic effects of single and repeated doses, however, as indicated below. The Toxicity Data Guide requires that tests should be carried out on the active ingredient and on the final formulation of the pesticide or veterinary product; any major changes in formulation are normally notified. The possibility that an increase in toxicity occurs when a formulation is stored for long periods should not be overlooked.

59. To test every class of compounds in current use for potentiation* effects would be an unjustifiable waste of limited resources. Only in special cases would it be necessary to specify individual compounds. The prediction of potentiation effects will be possible only when there is more information about the mode of action of different groups of active ingredients as mammalian poisons. In the meantime a critical examination of possible operator risks from successive or simultaneous exposure to mixtures of active ingredients might suggest a few combinations that ought to be tested for potentiation on laboratory mammals. We *recommend* that normally potentiation effects need only be considered in special instances and that a working document on potentiation should be prepared.

60. There is little point in asking applicants to improve chronic toxicity tests until evidence of the mode of action of a toxic active ingredient on mammals makes it possible to design better tests. It is more important that they should study the nature of the acute and sub-acute toxic effects of new active ingredients as soon as they come into extensive use, in order to design suitable long-term toxicity studies from which appropriate specific scientific information can be obtained. At present it is recommended that repeated administration be continued for 3–6 months to provide toxicity data for a first notification. The consensus of opinion among those testing drugs for toxicity is that any chronic effects will manifest themselves within a period of 3 months provided the doses are correctly adjusted so that they are in the range bordering on those that cause the death of the animal from the known acute toxic effects. If, in a way as yet unknown, some active ingredient does eventually prove capable of producing a toxic effect only after 1–2 years feeding to a rat, it should be remembered that this represents a major part of the rat's life span. Few people will be exposed to a new active ingredient in this way even during the first year or two of its introduction. Furthermore this will represent a small fraction of a human life span for those so exposed. It seems, therefore, quite rational to wait and see how the uses of a new active ingredient develop before considering whether the possibility of very long-term chronic effects developing in experimental animals should be examined.

61. The present guide to carcinogenicity testing is set out as an appendix to the Pesticides Safety Precautions Scheme. There are few specific tests for detecting carcinogenic activity in active ingredients apparently related to known carcinogens and no short-term animal test can be guaranteed either to disclose or to exclude carcinogenic activity in a new active ingredient. Reliance has to be placed upon observation on animals exposed to the active ingredient under investigation for the greater part of their lifetime in order to see whether an unusual incidence of tumours arises.

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* The Appendices and Working Documents to the Pesticides Safety Precautions Scheme and the Appendices to the Veterinary Products Safety Precautions Scheme have not been included in full in this report but are listed in paragraph 14 of Appendix 4. They are, however, included in the Schemes, published separately by the Ministry of Agriculture,

62. When it can reasonably be foreseen that long-term exposure of workers to a new active ingredient (or of consumers to foods containing residues of such) will occur, we *recommend* that studies should be made of possible toxic effects including carcinogenicity, from the continued administration of different doses over a long period. Licences permitting the sale of pesticide or veterinary products containing such active ingredients should be subject to review when the results of such tests, including special tests such as those referred to in the *Monthly Bulletin of the Ministry of Health and the Public Health Laboratory Service*, 1960, *19*, 108, become known.

63. A chronic toxic effect might include the persistence of the effects of a poison long after recovery from its acute effects. Thus methyl mercury compounds cause damage to brain cells in single doses and so can lead to a chronic and incurable neurological disability after accidental acute exposure to them. This type of chronic effect should be detected if the experimental animals surviving an LD_{50}* are observed for at least some weeks as now recommended. A more serious "chronic" effect has been observed with some poisons (not including active ingredients of pesticide or veterinary products), namely the development of cancer in animals months after giving a single dose. The existence of such a possibility could be a basis for requiring that reasonable numbers of animals should be used in the LD_{50} tests so as to ensure that a group of say 10 or 20 of those surviving an LD_{50} can be observed for their lifetime. For rats this will be for at least 2 years. This sort of information might reasonably be sought on any active ingredient not falling into one of the toxic groups to which so many existing active ingredients belong. We *recommend* that it should be asked for in the case of an active ingredient that has a striking acute toxic effect, the mechanism of which is completely unknown. It would be unreasonable to demand it in every instance.

64. We have noted that our Scientific Subcommittee is already considering these proposals and will discuss them with industrial toxicologists under the present arrangements for consultation with a view to revising the toxicological data which notifiers are required to supply in respect of risks from long-term effects including carcinogenesis and potentiation.

65. It is usual to follow the criterion that consumers should not take in more than one-hundredth part of the maximum no-effect level of an active ingredient to the most sensitive laboratory animal. The more that is known about the mode of action of an active ingredient and the more sensitive the tests for detecting any effects upon experimental animals, the more it becomes possible to use a realistic safety factor to take into account risks to the human consumer of food containing residues. It has been suggested that active ingredients should be classified according to the LD_{50} value determined in acute oral toxicity tests on laboratory animals and that the use of some active ingredients might be prohibited and the use of others restricted on this basis. We do not think that the hazards which an active ingredient might present to man can properly be assessed solely on the basis of its acute oral LD_{50} value for animals.

66. We have considered the desirability of testing new active ingredients for teratogenic* activity. In the absence of adequate testing procedures, we concluded that no case for a comprehensive test could be put forward at the present time. However, we *recommend* that, except for substances specifically intended to inhibit reproduction, evidence that animals receiving a sub-lethal dose of a product containing such a new active ingredient subsequently breed successfully should be obtained in all cases.

67. We were informed that a collaborative study was currently being carried out by medical toxicologists in industry and Government on methods of testing for percutaneous* toxicity. We hope that this work will shortly lead to agreement on a working document on this subject.

*Residue data and persistence**

68. At present data are required to assist in

(a) establishing a minimum interval between final application of the pesticide or veterinary product and the harvesting of the crop, the slaughter of the animal, the taking of eggs or of milk for human consumption, or the removal of foodstuffs from stores;

(b) assessing persistence.

The data now provided by notifiers are sufficient to indicate whether or not a residue occurs and, if so, whether it is likely to be of any toxicological significance to consumers. Whilst, say, fifty analyses, largely from "field trials", covering different rates of treatment, formulations, intervals from last application, location within the plant or animal and climatic conditions may be acceptable for this purpose, they may be insufficient for arriving at a figure for the likely maximum residues which may occur in the course of commercial use throughout this country. They are even less satisfactory for indicating the range of residues which will be found in practice under these conditions of use.

69. Where residues remain from one season to the next or for more than twelve months, the active ingredient concerned can be considered to be persistent. Persistence and toxicity may be interrelated but whilst persistence is often desirable for effective pest control, residues which persist in food and in the environment may be undesirable. The onus should be on the applicant for a licence for a pesticide or veterinary product to show that active ingredients which persist unnecessarily, or for longer than one year, are not dangerous.

70. We *recommend* that before being granted a licence not subject to review after a limited period the applicant for a licence for a pesticide or veterinary product containing a new active ingredient or requiring an increased dosage rate of toxic and persistent active ingredients should be required to submit adequate and realistic data from which it would be possible to assess the maximum residues likely to occur in recommended practice. These data should include rates of decay and should be obtained on a scale adequate to take account of the effects of the interval between final application and harvest or slaughter and, in the case of growing crops, of type of soil and climatic and other conditions in Great Britain. Field trials should be carried out under conditions similar to those in commercial use.

71. We further *recommend* that when residue data are required they should be provided for all crops on which use of a pesticide product is requested

unless there is good reason to believe that similar residues will be present in crops having a close botanical affinity, e.g. apples and pears. Within such a botanical group residue data should be provided on the more economically important species and should be obtained over a period of at least two seasons. During the first few years of a licence, the licensee of a pesticide or veterinary product should be at liberty to sell his product in accordance with the conditions as extensively as he can, but we *recommend* that he should still be under an obligation, if required by the licensing authority, to collect and furnish further residue data under practical conditions of use.

72. We consider it essential that, as with the existing schemes, suitable analytical methods for the determination of residues of hazardous or persistent active ingredients in both the treated crop or animal and in the environment should always be provided by the applicant before a licence for a pesticide or veterinary product is granted. Such methods should be made available by the applicant for publication in the normal scientific press or should be based on work already published therein. We *recommend* accordingly.

Research into very long-term effects

73. Some of the evidence received expressed concern about the lack of knowledge on the effects over a long period of minimal quantities of active ingredients in food and on possible adverse long-term effects of active ingredients on soil micro-fauna and micro-flora. We do not consider that evidence in respect of such effects should be expected of applicants under the terms of our proposed licensing scheme, but we agree that it is desirable that research into these problems should be undertaken. We have conveyed these views to the Research Committee on Toxic Chemicals.

*Phytotoxicity**

74. The immediate phytotoxic effects of a pesticide product are not taken into account when a notification is considered under the Pesticides Safety Precautions Scheme but are considered under the Agricultural Chemicals Approval Scheme when a pesticide product is submitted for approval.

75. Recently, a new aspect of phytotoxicity has been observed. The use of mulch or compost, made from straw which carried an acceptable residue (from the safety aspect) of the herbicide trichlorobenzoic acid, resulted in phytotoxic effects on certain sensitive crops. Similar effects might occur from the persistence of residues of this and other pesticide products in soil or on plant debris other than straw, though no case has yet been reported.

76. We are of the opinion that this aspect of persistence should be kept in mind when considering data submitted in support of an application for a licence for a pesticide product. We *recommend* that a working document on persistence should be prepared and should include reference to phytotoxic hazards from persistent herbicides.

*Food chains**

77. Since the phenomenon of concentration of active ingredients in food chains is wholly dependent on persistence, data on persistence are essential for the evaluation of food chain effects. It has been suggested that simplified food chains might be studied in the laboratory to assess risks in the field. Unfortunately natural ecosystems are so complex that it is not possible at present to devise a general laboratory test for cumulative food chain effects which will give an adequate forecast of what will happen in the field. We *recommend* that in default of a general test, assessments of food chain effects should be made taking into account (a) data from toxicity tests showing the levels of active ingredients which indicate poisoning; (b) data on persistence; (c) data on rates and extent of application.

Wild life hazards

78. The guide on the Provision of Information about Effects on Wild Life, contained in an appendix to the Pesticides Safety Precautions Scheme, and the working documents which give detailed advice on short-term risks to birds and on fish toxicity tests are, in our view, generally acceptable. However, although the survey for assessing risks to wild life, described in one of these working documents, has been used a number of times, it has not been tested for scientific validity in a control survey using one of the more toxic active ingredients. We *recommend* that at least one such official trial should be carried out and, if no bird deaths or other effects on wild life occur, the document should be reconsidered.

79. We noted that one of the working documents recommended an exposure period for fish of twenty-four hours. The desirability of extending this period to forty-eight hours or longer was considered but we came to the conclusion that an extension would be of no value, except possibly for selected individual pesticide and veterinary products. Whilst a laboratory test for the longer-term sub-lethal effects of persistent pesticide and veterinary products on fish was desirable, no simple general test of this kind appeared to be practicable. It was desirable to analyse fish submitted to the present standard test in order to estimate the residue levels associated with mortality.

80. We noted that, under present arrangements, there was no requirement laid on distributors to provide data on the effects of active ingredients on the hatchability of birds' eggs, on the reproductive capacity of birds and on the survival of young chicks. We consider that in the case of certain active ingredients, including the more persistent ones, such data should be provided in respect of domesticated birds. The difficulties of obtaining reliable data on effects on wild birds are such that we do not consider such tests on wild birds to be practicable. We note that our Scientific Subcommittee is already examining these requirements and that working documents setting out methods of conducting the appropriate tests will be issued in due course.

Field surveys

81. It is clear that the full effect of the introduction of a new active ingredient cannot be estimated unless trials closely simulate commercial practice. There is always a possibility that effects unforeseen in the laboratory may occur when a pesticide or veterinary product containing a new active ingredient is used under complex field conditions. The same applies when an existing active ingredient is used in a new way. We therefore *recommend* that when a licence

ingredients or using them in a new way, the licence should be subject to review after three years, and, where appropriate, also subject to scientifically designed field surveys being conducted by the licensee. These surveys should, where appropriate, include:

(a) medical observations on operators;

(b) adequate residue data, including where necessary the rate of disappearance of residues;

(c) wild life surveys.

82. Wild life field surveys should be organised by a trained biologist and should be based on the normal commercial use of the pesticide or veterinary product. Each survey should include trials of the type described in the appropriate working document to the Pesticides Safety Precautions Scheme together with an extensive enquiry to cover all the principal uses of the new active ingredient.

83. Data obtained over a period of at least two years should be reported within three years of the licence being granted. Clinical details of cases of suspected poisoning in man should always be obtained by medically qualified persons. Evidence from trials conducted to investigate user-safety in the early stages in the introduction of a new active ingredient should always be evaluated by medically qualified persons.

Independent testing for safety under a mandatory scheme

84. We have considered whether the proposed new mandatory scheme should provide for independent testing for safety of pesticide and veterinary products before they are licensed. Independent testing on behalf of the licensing authority would almost certainly have to apply to the great majority of submitted products and would be extremely expensive. We do not think that such testing would be an economic use of the resources of the State. The marginal increase in certainty about the absence of toxic hazards would not be commensurate with the amount of time, money and scientific resources which would have to be expended. In theory, it would be possible for an unscrupulous firm to falsify data submitted. But we think, in practice, it would not be easy to deceive the experts who would study the submitted data and no applicant for the licensing of such products and no scientist would be likely to run the risk to their reputation that discovery would entail or to jeopardise the public health by forging toxicity data. The licensing authority would be in a position to withhold or revoke the licence or to take proceedings for false information in such a case. We *recommend*, therefore, that provision of data by the applicant for the licensing of a product should be the basis of the proposed mandatory scheme. The licensing authority could of course institute independent tests if it thought there was a need to do so.

Comparison of the efficiency and other characteristics of one pesticide or veterinary product with another

85. We do not consider that under the proposed mandatory scheme the advisory committee should have to be fully satisfied of the comparative efficiency of any pesticide or veterinary product it recommended for licensing nor do we think that the present Agricultural Chemicals Approval Scheme should to lay down hard and fast rules for comparing the efficiency, toxicity or persistence of a new pesticide or veterinary product with those of others already on the market. However, in our recent review of persistent organochlorine pesticides*, we found it necessary to take account of all these matters and we are sure that the new committee, while it would not normally make such comparisons, should neither be barred from doing so nor be prevented from obtaining any relevant data on these matters. In particular, it should be able to require applicants for licences to substantiate any efficiency claims they make for their pesticide or veterinary products. We *recommend* accordingly.

IV. USE

General

86. However good and comprehensive a scheme may be for the control of the supply of pesticide and veterinary products many of these products may, if misused, be dangerous to the user, to the ultimate consumer of the treated crop or animal, or to wild life. It is only in rare cases that an active ingredient or a pesticide or veterinary product needs to be rejected outright on account of the risks that may arise from its use. There are regulations, which we describe later, to protect the employed worker who applies pesticide products in agriculture and, in the case of hydrogen cyanide, in food storage, but the safety of the user, of the consumer or of wild life depends very largely on the man who applies the product reading the label and observing the precautions thereon. In this part of our report we discuss what should be done in the control of use to protect all concerned.

Use of a pesticide or veterinary product after withdrawal or amendment of its licence

87. We have recommended that the proposed mandatory licensing scheme should include provision for the withdrawal of a licence for a pesticide or veterinary product. Such a withdrawal would make the sale or importation of the product concerned illegal but would not of itself place a ban on the use of stocks already sold. We think that it should be possible for Ministers to ban the use of the pesticide or veterinary product, if considered necessary, from a specified date and to prescribe the manner in which the stocks should be disposed of. Where a licence is amended because one existing use is not considered safe although other licensed uses may continue, we think it would be reasonable to leave the product concerned in the hands of the users to be used for a purpose still authorised. It would clearly be impracticable to withdraw it for relabelling and re-issue. We *recommend* accordingly.

Measures to secure proper use

88. It is, in our view, very important that all practical steps should be taken to ensure that pesticide and veterinary products are applied in accordance with

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* *Review of the Persistent Organochlorine Pesticides*
Report by the Advisory Committee on Poisonous Substances used in Agriculture and Food Storage: H.M.S.O. February 1964

the safety precautions on the label. Although the number of poisoning incidents known certainly to have been caused by the use of pesticide or veterinary products is relatively very small, there is a potential hazard in the use of these substances.

89. Misuse may be due to misinterpreting or even not reading the instructions for use as well as intentionally ignoring them. Examples of misuse include the overdosing of a crop, foodstuff or animal; using a pesticide or veterinary product for other than an authorised or recommended purpose; using it at the wrong time; and applying a pesticide product aerially to an area not intended for treatment. Misuse also arises if a crop is harvested or a food, such as an animal product (milk, eggs, meat), is sold within either the minimum recommended interval between last application and harvesting or before the end of the withdrawal period.

90. There may be occasions when the recommended application of a pesticide or veterinary product to an edible crop or to livestock leads to the presence of an unacceptable residue in the harvested crop or animal product because of a combination of circumstances beyond the control of the user. We believe such occasions to be very few. There are also occasions when a veterinary product, correctly applied, causes illness in treated animals. Such incidents are often unpredictable and some have defied explanation. Most commonly, however, such illness follows careless overdosage or administration at the wrong age or time. Finally, the recommended use of certain particularly persistent pesticide products has, on occasion, led to the undesirable contamination of the environment.

91. Misuse may lead to unnecessary hazards to the user, to the consumer, to livestock and to others, including wild life. It is not inevitable, however, that a misuse leads to harm. For example, the only result of overdosing an edible crop may be the extra expense to the user.

92. Risks to wild life from misuse are difficult to assess. In Great Britain the more deliberate misuses of pesticide products that are harmful to wild animals and birds are catered for, together with the use of other harmful chemicals and devices, under Acts for the Protection of Animals and of Birds. Similarly the provisions of the Rivers (Prevention of Pollution) Acts, the Water Resources Act and the Salmon and Fresh Water Fisheries Act, cater for the protection of fish and except for the Water Resources Act, there is comparable Scottish legislation (see Appendix 7).

93. Any attempt to control use is bound to produce enforcement difficulties and such control cannot therefore be made unduly onerous. On the other hand, we believe that all concerned will observe sensible provisions clearly designed for their own safety and that of others. The most obvious ways of proceeding are as follows:

(a) the licensing of all users of pesticide and veterinary products;

(b) the licensing of the users of some pesticide and veterinary products (e.g. those pesticide and veterinary products containing active ingredients scheduled under the Agriculture (Poisonous Substances) Regulations, or the Hydrogen Cyanide (Fumigation) Act or named in Parts A and B

(c) making the use of a pesticide product in contravention of the recommendations on the label an offence;

(d) making the use of a pesticide or veterinary product in certain ways which risk causing serious harm an offence.

94. The licensing of all users would be extremely burdensome, uncertain in its results and could only be even partially effective if a considerable apparatus of control was set up. We do not think that the dangers involved could possibly justify the expenditure of money and manpower that would be needed. The control of a restricted number of pesticides would still require a very elaborate apparatus of control. Further, the farmer is already required by law to ensure that his workers take certain precautions when using such products. He must acquaint himself with these precautions to avoid prosecution.

95. We have considered making it an offence to use any pesticide or veterinary product in contravention of the recommendations on the label but to do so would create a wide range of offences some of which would be purely technical and probably undetectable. It would clearly be undesirable to turn a large number of unimportant acts into offences and we do not therefore recommend that this course be adopted.

96. The best course would seem to be to limit the misuses which would be regarded as offences to the most important only. We *recommend* that the appropriate Ministers should have powers to make it an offence for employers or workers to misuse certain pesticide or veterinary products in certain specific ways. We suggest that these ways might include:—

(a) using a pesticide or veterinary product for a purpose in agriculture or food storage which is clearly in contravention of the licence of the product;

(b) deliberately over-dosing a crop, an animal or foodstuffs in store, with pesticide or veterinary products;

(c) harvesting a crop significantly before the end of the required period after application of a pesticide;

(d) continuing to use a pesticide or veterinary product for a purpose no longer included in the licence of the product;

(e) knowingly feeding dressed seed to animals or poultry;

(f) scattering dressed seed as a bait for wild birds;

(g) causing pesticide products containing certain active ingredients to be sprayed from the air.

97. Even such limited restrictions would not be easy to enforce, but provisions of this sort would give Ministers power to deal quickly with any gross misuses should they occur in the future.

Recording the use of pesticide and veterinary products

98. Regulations made under the Agriculture (Poisonous Substances) Act require certain records to be kept by commercial users whose employees use scheduled pesticide products and, in respect of occupiers of agricultural units, whose holdings (in terms of acreage of ground crops; or of bushes, climbing plants, including hops, and trees; or of greenhouses) exceed specified minimum acre-

laid down) in any period spent by employees applying scheduled pesticide products. The form in which the record is to be kept is not laid down but the record, whatever its form, must be retained for at least one year after the last entry. Employers who ensure that only they themselves apply scheduled pesticide products are not subject to the Regulations. There is no requirement to keep records of the use of pesticide products regulated under other Acts such as the Hydrogen Cyanide (Fumigation) Act and the Pharmacy and Poisons Act (see Appendix 7). Thus once strychnine for use against moles has been obtained under the Poisons Rules on the production of a permit there is no requirement to keep records of its use. To obtain a permit from the Divisional Office of the Ministry of Agriculture, Fisheries and Food, the user has to say exactly where the strychnine is to be used.

99. We consider that the statutory requirement to keep records of the use of certain pesticide products should be extended in two ways. Users of products containing active ingredients regulated under the Hydrogen Cyanide (Fumigation) Act and the Pharmacy and Poisons Act, whether they be users of pesticide products in food storage or users of veterinary products on farms, should keep such records. In addition, employers themselves and self-employed users should be required to keep records of use in agriculture and food storage of products scheduled or regulated under all three Acts. We *recommend* accordingly.

100. We further *recommend* that

(a) in addition to the requirements of the present Agriculture (Poisonous Substances) Regulations, it should be obligatory in the case of each pesticide or veterinary product for which records must be kept, to record in a prescribed form the following information:
  (i) the date of purchase and the quantity purchased;
  (ii) the use or uses to which the pesticide or veterinary product has been put with details of the date, quantity, type and extent of application, area and location of crop, numbers and description of animals treated, etc.

(b) such records should be kept for a period prescribed by the licensing authority.

These additional requirements would enhance the value of the records now kept, not only if a user becomes ill but also if misuse involving edible crops or livestock is alleged or if there is severe local environmental contamination.

Safety of users

101. The Agriculture (Poisonous Substances) Act (see Appendix 7) is designed to protect agricultural employees against harmful effects when applying pesticide products containing active ingredients scheduled in Regulations made under the Act. The purpose of the Act is to protect employees and it does not apply to commercial users who do not employ labour. Both employers and employees have certain obligations under the Regulations made under the Act. No operations have been specifically scheduled for the protection of users of veterinary products containing scheduled active ingredients, whilst Regulations to protect users in food storage cannot be made under the Act other than for those working made under the Hydrogen Cyanide (Fumigation) Act (see Appendix 7). There is no similar control of the use in food storage of any other active ingredient.

102. The operator protection research unit, set up in 1955 at the Ministry of Agriculture, Fisheries and Food's Plant Pathology Laboratory at Harpenden, obtained in consultation with medical experts, scientific evidence that assisted in the drafting and modification of the Agriculture (Poisonous Substances) Regulations. The need for this type of work was supported in the Report of the Sanders Research Study Group*. There is a continuing need for scientific investigation, with the full co-operation of medical experts, into possible hazards that may arise when applying pesticide products in agriculture and food storage.

103. So far as we are aware, few investigations have been made in this country into possible operator hazards arising from the application of veterinary products and few in relation to pesticide products used in food storage with the exception of the fumigant methyl bromide. Extensive investigations have been made on methyl bromide which have confirmed that sufficient hazards are involved in its use to justify statutory control. In spite of the absence of scientific evidence of hazard arising from some of these uses, we consider:

(a) that the Agriculture (Poisonous Substances) Regulations should be amended to make certain uses of veterinary products containing scheduled active ingredients scheduled operations requiring the use of protective clothing;

(b) that the Agriculture (Poisonous Substances) Act 1952 should be amended to cover the use of pesticide products in food storage;

(c) that the Agriculture (Poisonous Substances) Act 1952 should be amended to make it applicable to commercial users in agriculture and food storage who do not employ labour as well as those who do;

(d) that additional facilities and staff should be provided to enable the operator protection research unit, described in para. 102 to obtain more speedily information on the hazards to those applying pesticide products and to workers after such applications; and that new facilities and staff be provided to get comparable information in respect of veterinary products;

(e) that the provisions of the Hydrogen Cyanide (Fumigation) Act 1937 should be applied by Order in Council, to fumigation with methyl bromide and that its use in food storage should be covered by Regulations under that Act.

Investigating cases of poisoning

104. Under the Agriculture (Poisonous Substances) Regulations, an employer is required to report to a Safety Inspector cases of alleged poisoning of his employees arising from the use of scheduled pesticide products. We consider it important that all cases of suspected poisoning by any pesticide or veterinary product should be immediately reported so that they can be investigated as early as possible after occurrence and the Advisory Committee warned of any apparently new hazard. We *recommend* accordingly.

* "Toxic Chemicals in Agriculture and Food Storage": Report of the Research Study

Safety of workers and other persons, following the use of pesticide and veterinary products

105. There are provisions in the Agriculture (Poisonous Substances) Regulations for the protection of workers other than operators or users. They apply to those who handle hops that have been sprayed less than 24 hours earlier with TEPP or mevinphos, or less than 4 days earlier with certain other active ingredients listed in those Regulations; and to those who have cause to enter greenhouses which earlier have been treated with scheduled pesticide products. The Regulations made under the Hydrogen Cyanide (Fumigation) Act make provision for the protection of workers and third parties who need to enter buildings or ships that have been fumigated with this chemical. No other statutory provisions for the protection of workers exist in respect of agriculture or food storage but official recommendations on the safe use of active ingredients and veterinary products often include advice on the protection of workers.

106. There is a lack of scientific information, except in respect of a few fumigants used in food storage, on the risks to those who handle treated crops, foodstuffs or livestock or who enter premises after treatment. Additional information is required and we have recommended in paragraph 103(d) above that additional facilities should be provided to obtain it.

107. The erection of notices warning the public and workers against entering a greenhouse before a certain time after treatment is required under the Agriculture (Poisonous Substances) Regulations when a scheduled pesticide product has been used in that greenhouse.

108. In food storage, a similar requirement exists only for buildings or ships when hydrogen cyanide is used, although it would apply also to methyl bromide if our recommendation in paragraph 103(e) above were to be put into effect. We believe that consideration should be given to requiring warning notices to be posted around food storage premises following treatment with certain pesticide products (e.g. liquid fumigants) and to ways of making such requirements effective and we *recommend* accordingly.

109. It might be argued that similar notices should be put round treated fields. Clearly the user of a pesticide product should ensure that he does not put other people at risk. But it is unlikely that passers-by or workers would go into fields that are in the process of being treated and we are advised that, in general, once the spray on a treated crop has dried, men and animals can safely come in contact with it. We know of no authenticated case where anyone has been harmed through entering a field and walking through a crop after the spray has dried. We have no information whether there are any risks to passers-by or workers who go into a field that has recently been dusted, probably because dusts are little used in this country. The operator protection research unit might well investigate this subject but, unless such an enquiry reveals unexpected hazards, we do not think that a requirement to erect warning notices round a treated field would be justified.

110. We are aware of alleged cases of harm being caused to trespassers who picked and ate recently treated fruits and vegetables and to passers-by, especially children, who gathered and ate ripe wild fruits from hedgerows which had been grazed on or in the vicinity of treated crops, in particular to sheep poisoned by copper after grazing in orchards, have also been reported. We think some of these problems can be dealt with by commonsense, care and education. The contamination of wild fruit can only be prevented by more careful application and this cannot be achieved directly by statutory control.

Aerial application of pesticide products

111. There are clearly dangers to third parties from aircraft which apply pesticide products crashing or jettisonning their load in an emergency. There can also be danger to third parties through misapplication of the spray or dust through pilot error. In addition, we accept that mature crops, if accidentally contaminated by aircraft spraying beyond the prescribed area, might contain undesirable residues at the time of harvest, if the interval between accidental treatment and harvesting were comparatively short. The aerial application of pesticide products is controlled by the Board of Trade; the Air Navigation Order 1960 empowers the Board to grant to an "operator" of one or more named aircraft an "agricultural aviation exemption" from any provision of the Order or of subsidiary Regulations. In this context, an "operator" is a person who is responsible for the management of aircraft and therefore is aware of and controls the pesticide products applied in this way. There are about a dozen operators currently in possession of agricultural aviation exemptions in the United Kingdom.

112. An agricultural aviation exemption gives exemption from Regulations relating to the dropping of articles from aircraft (provided they do not endanger persons or property) and to low flying (other than over a congested area or a crowd). At the same time, conditions can be laid down in an agricultural aviation exemption and these at present include the prohibition of the use of parathion in any form and six other toxic organophosphorus compounds (namely amiton, demeton, mevinphos, mipafox, sulfotep and TEPP [HETP]) unless in granular form.

113. Agricultural aviation exemptions are normally granted for a period of 12 months but they may be issued for shorter periods (e.g. to a new operator or a foreign operator working in the United Kingdom for a limited season only). They may be revoked without consultation if any of the conditions need to be altered or there is a change of aircraft. Normally a new exemption is issued immediately as was done when the aerial application of the six toxic organophosphorus compounds mentioned above was prohibited.

114. We are informed that in the near future, the Board of Trade proposes to require that before an operator is issued with an agricultural aviation exemption, he should prepare and have available a suitable "Operations Manual" in which, under a number of headings specified by the Board, he will state the operating rules to which his company works. It is not proposed that there should be formal approval of the Operations Manual, but the Board would ask the operator to justify any entry which appears to imply an undesirably low standard. Failure to comply with the relevant Operations Manual would not be made an offence, but operators would be aware that the Board may